

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION)
THIS DOCUMENT RELATES TO:) Master File No. 01-CV-12257-PBS
State of Montana v. Abbott Labs Inc., et al.,) Judge Patti B. Saris
Cause No. CV-02-09-H-DWM (D. Mont.))
)

**INDIVIDUAL MEMORANDUM OF LAW OF
DEFENDANT ASTRAZENECA PHARMACEUTICALS LP
IN OPPOSITION TO THE STATE OF MONTANA'S MOTION
FOR PARTIAL SUMMARY JUDGMENT AGAINST CERTAIN DEFENDANTS**

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PRELIMINARY STATEMENT

Defendant AstraZeneca Pharmaceuticals LP (“AstraZeneca”)¹ respectfully submits this memorandum of law in opposition to the State of Montana’s (the “State’s”) motion for partial summary judgment.

In its motion for partial summary judgment, the State of Montana claims that “Defendants’ creation, publication or assistance in the publication of false AWPs violated the Montana Medicaid [F]raud [S]tatute’s proscriptions against the making of false statements in connection with State Medicaid reimbursement.” The State of Montana’s Memorandum in Support of Motion for Partial Summary Judgment Against Certain Defendants (“Pl.’s Mem.”) at 1. The State’s motion should be denied because the record does not establish that (1) the AWPs for AstraZeneca’s products reported in various pricing compendia were “false;” (2) AstraZeneca was responsible for the publication of AWPs in these pricing compendia; and (3) AstraZeneca made any statements—let alone “false” ones—“in connection with State Medicaid reimbursement.” Moreover, the record does not establish that the “State set its Medicaid reimbursement formula based on the plain meaning of AWP after analyzing the market place as an attempt to set a fair market price.” *Id.* at 3.

Further, the statute upon which the State’s motion for partial summary judgment is based—the Montana Medicaid Fraud Statute—is not applicable to pharmaceutical manufacturers such as AstraZeneca in this matter.

¹ Although named as Defendants, Zeneca, Inc. and AstraZeneca PLC have never been served with the State of Montana’s Second Amended Complaint. The entity identified in the Second Amended Complaint as AstraZeneca U.S. does not exist.

Finally, as set forth in the Defendants' Memorandum in Support of Defendants' Joint Opposition to the State of Montana's Motion for Partial Summary Judgment Against Certain Defendants ("Joint Opposition" or "Joint Opp."), there is an abundance of evidence in the record that establishes that the State knew for many years that AWP was a pricing benchmark, rather than an *actual* average of wholesale prices for prescription drugs. *See id.* at 1-4; *see also* Defendants' Memorandum in Support of Defendants' Joint Motion for Summary Judgment, Feb. 8, 2007 (Docket No. 3647) ("Joint Memorandum" or "Joint Mem."), at 3-20.²

ARGUMENT

I. The State's Motion For Partial Summary Judgment Should Be Denied Because It Fails To Provide Proof That AstraZeneca Violated The Montana Medicaid Fraud Statute.

A. The Montana Medicaid Fraud Statute Is Not Applicable To Pharmaceutical Manufacturers Such As AstraZeneca.

As discussed at length in Defendants' Joint Opposition, *id.* at 6-9, the provisions of the Montana Medicaid Fraud Statute, MONT. CODE ANN. §§ 53-6-143(4) and 53-6-160, do not apply to attenuated, non-provider entities such as AstraZeneca. *See also* Joint Mem. at 30-32. As an initial matter, under Montana law, Medicaid fraud claims may be asserted *only* against persons or entities who have "submit[ted] to a [M]edicaid agency an application, claim, report, document,

² AstraZeneca incorporates by reference (1) Defendants' Statement of Undisputed Material Facts in Support of Defendants' Motion for Summary Judgment, Feb. 8, 2007 (Docket No. 3648) ("Joint 56.1 Stmt."); (2) Defendants' Joint Response to the State of Montana's Statement of Undisputed Material Facts in Support of Its Motion for Partial Summary Judgment Against Certain Defendants and Supplemental Statement of Undisputed Facts ("Joint Response 56.1 Stmt."); and (3) Local Rule 56.1 Statement of Undisputed Material Facts in Further Support of Defendant AstraZeneca Pharmaceutical LP's Motion for Summary Judgment, Feb. 8, 2007 (Docket No. 3697) ("AstraZeneca 56.1 Stmt."). In addition, responses specific to AstraZeneca are set forth in its individual Counter Statement of Disputed Facts in Response to the State of Montana's L.R. 56.1 Statement of Undisputed Material Facts in Support of Motion for Partial Summary Judgment Against Certain Defendants ("AstraZeneca Counter 56.1 Stmt.").

or other information.” MONT. CODE ANN. § 53-6-160(1).³ Second, the Medicaid Fraud Statute makes it clear that it is “providers” who are charged with the duty to submit accurate and truthful Medicaid claims. *Id.* §§ 53-6-160(2)(a)-(b).⁴ “Provider” is a defined term under the Statute that brings within the reach of the fraud provision *only* entities “that [have] enrolled or applied to enroll as a provider of services or items under [Medicaid].” *Id.* § 53-6-155(13).⁵ It is undisputed both that AstraZeneca did not “submit” any “application, claim, report, document, or other information” to any Medicaid agency and that AstraZeneca is not a “provider.” *See* Joint 56.1 Stmt. ¶ 103, Ex. 62; ¶ 105, Ex. 82.

In an attempt to circumvent these legal hurdles, the State argues that Defendants should be held liable pursuant to section 53-6-160(4) of the Medicaid Fraud Statute for *indirect* statements or representations; *i.e.*, that Defendants violated the Statute by submitting to third-party pricing compendium First DataBank allegedly untrue and incomplete information about their AWPs. *See* Pl.’s Mem. at 14-17.

³ Section 53-6-160(1) provides:

A person who submits to a [M]edicaid agency an application, claim, report, document, or other information that is or may be used to determine eligibility for [M]edicaid benefits, eligibility to participate as a provider, or the right to or the amount of payment under the [M]edicaid program is considered to represent to the department, to the best of the person’s knowledge and belief, that the item is genuine and that its contents, including all statements, claims, and representations contained in the document, are true, complete, accurate, and not misleading.

MONT. CODE ANN. § 53-6-160(1).

⁴ A “provider has a duty to exercise reasonable care to ensure the truthfulness, completeness, and accuracy” of all claims and statements submitted to the Medicaid agency, and to ensure that a claim made for payment or reimbursement under the Medicaid program is one for which the provider is entitled to receive payment. *See* MONT. CODE. ANN. §§ 53-6-160(2)(a)-(b) (emphasis added).

⁵ The statute explicitly limits the definition of “provider” to “an individual, company, partnership, corporation, institution, facility, or other entity or business association that has enrolled or applied to enroll as a provider of services or items under the medical assistance program established under this part.” MONT. CODE ANN. § 53-6-155(13).

Section 53-6-160(4) of the Montana Medicaid Fraud Statute provides:

A person is considered to have made or to have authorized to be made a claim, statement, or representation if the person:

- (a) had the authority or responsibility to:
 - (i) make the claim, statement, or representation;
 - (ii) supervise another who made the claim, statement, or representation; or
 - (iii) authorize the making of the claim, statement, or representation, whether by operation of law, business or professional practice, or office policy or procedure; and
- (b) exercised or failed to exercise that authority or responsibility and, as a direct or indirect result, the false statement was made, resulting in a claim for a service or item when the person knew or had reason to know that the person was not entitled under applicable statutes, regulations, rules, or policies to [M]edicaid payment or benefits for the service or item or for the amount of payment requested or claimed.

MONT. CODE ANN. § 53-6-160(4).

The State's attempted application of section 53-6-160(4) to AstraZeneca's communications with third-party First DataBank stretches the Medicaid Fraud Statute beyond its intended scope and meaning. The Statute is intended to combat fraud by "providers," such as physicians and pharmacies who submit claims for payment to, and receive reimbursement from, the Montana Medicaid program. *See* MONT. CODE ANN. §§ 53-6-160(2)-(3) (setting penalties against a "provider" who receives payment to which he is not entitled).⁶

⁶ See also Minutes of the Montana Senate Public Health, Welfare and Safety Committee, Feb. 17, 1995, at 8. Nancy Ellery, Director of Montana's Medicaid program, testified that the Medicaid Fraud Statute was directed at fraud by providers themselves. Ellery listed several examples of provider-specific practices that the Statute was intended to combat, such as "bill[ing] for services not provided, bill[ing] twice for the same service...and bill[ing] for unnecessary services." See Joint 56.1 Stmt., ¶ 106, Ex. 79.

Moreover, the legislative history surrounding section 53-6-160(4) establishes that this section was intended to reach only the conduct of persons or entities acting *under the supervision or authority of a Medicaid provider* who actually receives payment from the State's Medicaid program. Indeed, in explaining Montana Medicaid's understanding of this section, Nancy Ellery—the Director of Montana's Medicaid program at the time—wrote that:

The third key element in this statement of responsibility is the principle that the provider, who receives the benefit of the [M]edicaid payment, *must exercise supervision over and take responsibility for the acts of their employees that bill the [M]edicaid program on the provider's behalf*. Without such a responsibility, it is too easy for a provider to accept the benefit of improper or even dishonest billing, but then when confronted with the impropriety or dishonesty, to disclaim knowledge or responsibility. Subsection (3) would prevent a person from disclaiming knowledge if the person knew of the impropriety or, by virtue of their position, authority or responsibility should have known of the impropriety. Subsection (4) would prevent a person from avoiding responsibility if the person's failure to exercise actual authority or responsibility caused the improper conduct to occur.

Joint Response 56.1 Stmt. ¶ 6, Ex. 3 (Letter from Nancy Ellery to Representative Duane Grimes, March 13, 1995) (emphasis added).

In addition, in testimony before the Montana House's Human Services and Aging Committee, Greg Gould—Legal Counsel for the State's Department of Social and Rehabilitation Services—explained the Department's understanding of the purpose of proposed section 53-6-160(4).

Rep. Simon asked for clarification as to the purpose of [the section]. Mr. Gould reiterated that it is *not* the intent to *overreach* and the purpose is to address the problem of *supervisors* attempting to escape the responsibility of repaying overpayment. It is important to show that they have a responsibility *to supervise their employees* who submit claims on their behalf.

Joint Response 56.1 Stmt. ¶ 7, Ex. 6 (Testimony of Greg Gould at Hearing on S.B. 293, March 10, 1995, at 5) (emphasis added).

Thus, the language, context, and legislative history of section 53-6-160(4) make it clear that this section of the Medicaid Fraud Statute was not intended to reach the conduct of attenuated, non-provider entities such as pharmaceutical manufacturers. Accordingly, the State's motion for partial summary judgment as against AstraZeneca should be denied.

B. It Is Not Undisputed That AstraZeneca Controlled The AWPs For Its Drugs That Were Published By First DataBank.

The State's motion for partial summary judgment assumes that, for AstraZeneca's products, AstraZeneca defrauded the State by controlling and causing to be published allegedly "false" AWPs. As an initial matter, as previously stated, the record establishes that the reported AWPs were understood by the State, AstraZeneca, and the industry at large to be pricing benchmarks that typically bear a formulaic mathematical relationship to AstraZeneca's list prices, known as Wholesale Acquisition Costs ("WACs").

The State acknowledges that the "Montana Medicaid [p]rogram uses the AWP[s] as reported through *First DataBank*," and not any other pricing compendium. Pl.'s Mem. at 4. In arguing that AstraZeneca directly controlled the AWPs published by First DataBank for its respective drugs, the State relies almost exclusively on the trial testimony of AstraZeneca employee Steve Buckanavage. *See id.* at 4-5, n.7. Mr. Buckanavage's testimony, however, deals with AstraZeneca's reporting of suggested AWPs to Red Book, *see* AstraZeneca Counter 56.1 Stmt. at 2-3, Ex. 1 (Deposition of Steve Buckanavage, dated June 8, 2005, at 147), a pricing compendium not relied upon by the Montana Medicaid program. Thus, Mr. Buckanavage's

testimony is irrelevant to the issue of whether AstraZeneca directly controlled the published AWPs that were ultimately relied on by Montana Medicaid in setting its reimbursement rates.

On the other hand, Patricia Kay Morgan, the Manager of Product Knowledge-Based Services at First DataBank, testified that the AWPs published by First DataBank were not set by the pharmaceutical manufacturers, but instead by First DataBank itself based on wholesaler surveys. *See* AstraZeneca Counter 56.1 Stmt. at 3, Ex. 3 (Deposition of Patricia Kay Morgan, dated January 11, 2005 (“Morgan II Dep.”), at 26-27, 36). Ms. Morgan testified as follows:

Q: Okay. SWP, what does that refer to?

A: It’s the suggested wholesale price, and it’s populated if the manufacturer suggests an AWP.

Q: Some manufacturers include an AWP on their price lists; is that correct?

A: A suggested AWP, yes.

Q: And that’s where you put that into what you call the SWP field?

A: That’s correct.

Q: What is Blue Book price?

A: Blue Book is what’s become synonymous with AWP to many of our customers, so it is the average wholesale price, so it’s the price that includes the markup after our wholesaler survey, if the product’s available through the wholesaler.

Id. at 36; *see also* AstraZeneca Counter 56.1 Stmt. at 3, Ex. 2 (Deposition of Patricia Kay Morgan, dated January 28, 2002 (“Morgan I Dep.”), at 68-69) (testifying that manufacturers do not set AWP for First DataBank “[b]ecause we survey wholesalers”).

Ms. Morgan also testified that, even when pharmaceutical manufacturers submitted “suggested AWPs,” they were disregarded by First DataBank when determining what AWP percentage mark-up to employ. *See* AstraZeneca Counter 56.1 Stmt. at 3, Ex. 2 (Morgan I Dep. at 71) (“[Manufacturers] send suggested AWPs, but that’s not my definition, so whatever they

put down is irrelevant to me.”); *id.* (“[Manufacturers] can suggest [an AWP]. If it happens to disagree with the wholesaler, we go with the wholesaler’s price.”).

Finally, Ms. Morgan testified that while AstraZeneca had submitted “suggested” AWPs for its drugs, these were often disregarded in setting the published AWPs. *See* AstraZeneca Counter 56.1 Stmt. at 3, Ex. 3 (Morgan II Dep. at 111-12) (noting that AstraZeneca’s “suggested” AWP differed from the AWP published by First DataBank, and stating that she had no reason “to believe that it was changed for any reason other than [the] usual practice of surveying wholesalers and populating [the First DataBank] database”).

II. The State’s Motion For Partial Summary Judgment Should Be Denied Because It Cannot Show That It Was Deceived Or Defrauded With Respect To The Pricing Of AstraZeneca’s Drugs.

Essential to the State’s claims under the Montana Medicaid Fraud Statute is a showing of deception or fraud. *See* MONT. CODE. ANN. § 53-6-160 (Medicaid Fraud Statute requires “[t]ruthfulness, completeness, and accuracy of submissions to [M]edicaid agencies”). Courts interpreting fraud claims under Montana law have found that when a plaintiff has knowledge of the allegedly deceptive or fraudulent conduct at issue, there can be no viable cause of action. *See, e.g., Lee v. Stockmen’s Nat’l Bank*, 207 P. 623, 630 (Mont. 1922) (“[O]ne can secure no redress for a misrepresentation, which he knew to be false, nor for failure to disclose facts which he knew to exist. *If the representee knew the truth, it is obvious that he was neither deceived nor defrauded, and that any loss he may sustain is not traceable to the representations, but is in effect self-inflicted.*”) (emphasis added); *Spence v. Yocum*, 651 P.2d 1022, 1025 (Mont. 1982) (citing *Lee*); cf. *Starr v. The Summit, Inc.*, No. DV 00-20, 2003 Mont. Dist. LEXIS 2451 (Carbon County District Court, July 10, 2003) (holding that there was no deception under Montana’s

consumer protection statute where the plaintiff had constructive knowledge of the alleged misrepresentation).

The State has not demonstrated that AstraZeneca engaged in conduct that deceived or defrauded the State. Indeed, the record in this case establishes that the State knew for many years that AWP is a pricing benchmark, rather than an *actual* average of wholesale prices. *See Joint Mem.* at 3–20. In fact, Montana deliberately chose to use AWP as a pricing benchmark in its Medicaid reimbursement system, while knowing that AWPs did not equal average wholesale prices. *See AstraZeneca 56.1 Stmt.* ¶ 16.

The record establishes that the State was not deceived regarding the sales prices of AstraZeneca’s various products because Montana hospitals, universities, prisons, and other non-Medicaid State entities purchased significant volumes of AstraZeneca drugs at prices *below* the Montana Medicaid ingredient cost reimbursement rate. *See id.* ¶ 21. The State has not altered the way it reimburses for these AstraZeneca drugs under its Medicaid program. This lack of change in reimbursement methodology is a strong indication that the State was never deceived or defrauded by any purported misrepresentations by AstraZeneca in establishing its reimbursement rates. *See Schweigert v. Fowler*, 784 P.2d 405, 428-29 (Mont. 1990) (noting that a plaintiff cannot establish reliance on a fraud claim where the plaintiff knew the truth behind the alleged misrepresentation); *Commodity Credit Corp. v. Rosenberg Bros.*, 243 F.2d 504, 512 (9th Cir. 1957) (“Even in cases where a party has been fraudulently induced … it follows that if, after full

knowledge of the fraud or deceit, he goes forward and executes it notwithstanding such fraud, the damage which he thereby sustains is voluntarily incurred.”).⁷

Thus, because the State cannot prove its central and essential allegation of deception, its motion for partial summary judgment should be denied.

⁷ Likewise, AstraZeneca has reported average sales price (“ASP”) data to the State for certain of its drugs since 2003. *See AstraZeneca 56.1 Stmt. ¶ 20.* Nevertheless, Montana has not changed its AWP-based methodology for reimbursing for these drugs or any others.

CONCLUSION

For the foregoing reasons, as well as those set forth in Defendants' Joint Opposition, the State of Montana's motion for partial summary judgment against certain defendants should be denied.

Dated: Boston, Massachusetts
March 22, 2007

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2007, I caused a true and correct copy of the foregoing, the Individual Memorandum of Law of Defendant AstraZeneca Pharmaceuticals LP in Opposition to the State of Montana's Motion for Partial Summary Judgment Against Certain Defendants, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 in MDL No. 1456.

/s/ Katherine B. Schmeckpeper
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